UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

LOUISIANA WHOLESALE DRUG CO., INC., Plaintiff,	:	
against-	:	**07 CV 7343 (HB)**
	:	**OPINION & ORDER**
SANOFI-AVENTIS, SANOFI-AVENTIS U.S., LLC and AVENTIS PHARMACEUTICALS, INC.,	:	
Defendants.	:	

Hon. HAROLD BAER, JR., District Judge:

Louisiana-Wholesale Drug Company ("Louisiana Wholesale" or "Plaintiff") filed a complaint on August 17, 2007 alleging that Aventis Pharmaceuticals, Inc. ("Aventis"), Sanofi-Aventis, and Sanofi-Aventi U.S., LLC ("Defendants") violated antitrust law under Section 2 of the Sherman Act, 15 U.S.C. § 2 when it filed an allegedly sham Citizen-Petition with the Federal Drug Administration ("FDA") to block the approval of five generic manufacturers' Abbreviated New Drug Applications ("ANDA") to market a generic version of Aventis' rheumatoid-arthritis drug leflunomide, called Arava. Defendants move for summary judgment under Federal Rule of Civil Procedure 56. Defendants also move to exclude the Plaintiffs' Expert Martha M. Bennett and to strike Plaintiffs' Rule 56.1 Statement. For the reasons set forth below, all three motions are denied.

I. FACTS

The underlying facts of this case are found in the opinion and order denying Defendants' motion to dismiss the complaint, familiarity with which is presumed. Order Denying Mot. to Dismiss, Jan. 18, 2008. Here, Plaintiffs allege that the Citizen Petition delay the entry of generic leflunomide into the market, which would have permitted sale of the generic drug at prices significantly below Defendants' prices for Arava, the brand version of leflunomide. Compl. ¶ 83. Defendant Aventis acquired the exclusive right to market Arava in 10 mg, 20 mg and 100 mg strengths for five years and six months on September 10, 1998.[1] (Def. 56.1 SOF ¶¶ 15, 18.)

[1] The earliest date the ANDAs could have been filed by generic manufacturers was September 2002, one year prior to expiration of Aventis's patent for Arava, in the form of challenges to the patent. (Pl. 56.1 Response ¶ 24.) Aventis de-listed the patent for Arava in August 2002 at which point no challenge to the patent was feasible prior to the five year period of marketing. Id. The six month extension for pediatric marketing exclusivity under 21 U.S.C. § 355a extended the exclusivity to March 10, 2004. (Def. SOF ¶¶ 23, 31.)

Six generic manufacturers (Kali, Apotex, Barr, Teva, Eon, and Sandoz) submitted ANDAs seeking permission to market and sell 10 mg and 20 mg, but not the 100 mg, dosages of generic leflunomide on March 10, 2004, the date of expiration of Aventis' exclusive marketing period under section 505(j)(5)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) and section 505(c)(3)(E)(ii) (21 U.S.C. §355(c)). (Def. 56.1 SOF ¶ 178.) Aventis stopped selling the 100 mg dose and provided it to physicians free of charge as of January 2002. (Bennett Expert Report 13; Def. 56.1 SOF ¶¶ 19-20.) The FDA is required to keep the existence and contents of ANDAs confidential unless and until the agency approves them, thus Defendants could anticipate, but could not know when generic manufacturers would apply for an ANDA or what they would request in their application. 21 C.R.F. § 314.430(b), (d).

Defendants learned on September 17, 2004 that a pharmaceutical company received approval to market generic leflunomide in Canada for the 10 mg and 20 mg tablets,[2] prompting Defendants to question whether manufacturers might seek FDA approval to market only the 10 and 20 mg tablets in the United States without providing the 100 mg tablet loading dose.[3] (Def. 56.1 SOF ¶ 36.) Defendants also "suspected that leflunomide ANDA filers in the United States might try to substitute five 20 mg tablets in place of the one 100 mg loading dose tablet recommended in Arava's label, or might seek to omit the 100 mg loading dose tablet from their label altogether." (Def. 56.1 SOF ¶ 40.) The Defendants, led by the "Life Cycle Management Group,"[4] purportedly spent the next six months researching other drug products with a "two-part dosing regimen" and FDA regulations regarding labeling. (Def. 56.1 SOF ¶¶ 36-72.) Defendants filed a Citizen Petition on March 31, 2005—one year after the Defendants' period of exclusivity had ended and one year into FDA review of the ANDA submissions. (Def. Ex. 40.)

Aventis's Petition requested that:

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[2] The Defendants learned in February 2005 that the companies marketing in Canada did in fact reference the 100 mg loading dose in their label. (Pl. 56.1 Response ¶ 36, PEx. 32.) Thus, the basis for Defendants' Petition-- that they were concerned that U.S. generic manufacturers would similarly market the drug without mentioning or producing the 100 mg loading dose--was not only speculative, but completely undermined by this revelation.

[3] The 100 mg strength served as a loading dose to be taken for three days to "quickly reach steady state plasma concentrations" of the metabolized form of leflunomide. (See Compl., Exh. 1, at 2.) Aventis stopped selling the 100-mg tablet in pharmacies in January 2002, but continued distribution at no charge to physicians via blister packs of three tablets for the loading dose. (Def. Rule 56.1 SOF ¶¶ 19-20.)

[4] The Life Cycle Management Group, or the "Life Cycle Prolongation Department" is a unit charged with evaluating potential life cycle management projects, i.e. to prolong sales of Defendants' products. (Pl. 56.1 SOAF ¶ 24, Def. Ex. 27, Gardella Tr. 20:20-21:15.) The mission statement of the group is to "mitigate generic erosion and to prolong, as much as possible, the life cycle of our products." (Pl. 56.1 SOAF ¶ 24.)

> [I]f an ANDA applicant is not seeking approval of a 100 mg leflunomide tablet that is bioequivalent to Arava® 100 mg tablets, the FDA requires the applicant to perform in vivo bioequivalence testing to confirm that five of its 20 mg tablets are bioequivalent to one Arava® 100 mg tablet. Aventis further requests that the agency withhold final approval of any ANDA that (1) does not seek approval of a 100 mg leflunomide tablet that is bioequivalent to Arava® 100 mg or (2) does not establish in vivo bioequivalence between five 20 mg leflunomide tablets and one Arava® 100 mg tablet.

(Def. Ex. 40, Citizen Petition, March 31, 2005.) In a supplemental submission to the FDA on June 10, 2005, Aventis stated the following:

> [I]f a generic applicant does not seek approval of a 100 mg tablet, Aventis maintains that the applicant must establish that five of its 20 mg tablets are bioequivalent to one 100 mg Arava tablet. Otherwise, it may not label its product so as to permit the use of five 20 mg tablets as an alternative loading dose. The label would thus have to either omit the loading dose or reference a 100 mg tablet that the generic does not manufacture. Neither option should be permitted.

(D. Ex. 13, Aventis Submission to FDA, June 10, 2005.)

The FDA reviewed the six ANDA applications examining issues of chemistry, bioequivalence, labeling, and registration. (See Def. 56.1 SOF ¶¶ 148-176.) These six manufacturers drafted about a dozen or so amendments in response to issues raised in review. (See Def. 56.1 SOF ¶¶ 177-278; see also Bennett Rep.) The FDA addressed four types of issues with the ANDAs after March 31, 2005: labeling; dissolution specifications; toxicity specifications for a substance called TFMA which occurred in the active pharmaceutical ingredient of leflunomide; and enlistment in pregnancy registries. (See Bennett Rep.) These were all transmitted and resolved between the FDA and the generics via "Minor" and "Telephone" Amendments. (See Bennett Rep.)

Over one year into review of the ANDAs, and three months after the Citizen Petition was filed, the FDA informed the generics on June 2, 2005 that they would not receive final approval before the FDA resolved the regulatory issues raised in the Petition. (PEx. 140.) The last amendments to each application were made on the following dates: Kali, August 23, 2005; Apotex August 26, 2005; Teva, July 19, 2005; Barr, August 4, 2005; Eon, September 8, 2005; Sandoz, September 9, 2005. (Def. 56.1 SOF ¶¶ 180-185.)

Each manufacturer, except Eon, which was acquired by Sandoz, had produced and bottled a final product by June 2005 for launch, and which eventually was sold and distributed

subsequent to the September 13th approval, even though amendments to labeling and more importantly, to the TFMA and dissolution specifications were still underway. (See Bennett Rep.) These launch quantities were all ultimately sold without alteration. (Id.; see also Pendergast Tr. 328:12-329:7.)

The FDA must resolve Citizen Petitions within 180 days of filing. 21 C.F.R. §10.30(e)(2.) On September 13, 2005, just under the 180-day limit, the FDA denied Aventis's Petition *in toto*. (Def. Ex. 73.) The ANDAs were all formally approved on the same day. (Def. 56.1 SOF ¶ 281.)

Procedural History

Defendants' motion to dismiss the complaint was denied on January 18, 2008. A Direct Purchaser Class was certified by stipulation on April 10, 2008. (Docket # 109.) A hearing on the motions for summary judgment and to exclude the expert's testimony was held on October 1, 2008.

II. LEGAL STANDARD

Summary judgment is only appropriate if a rational trier of fact could not find for the non-movant when viewing the evidence produced in the light most favorable to the non-movant. Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). The burden to demonstrate that there is no genuine issue of material fact for the jury rests with the movant. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986); FDIC v. Giametti, 34 F.3d 51, 54 (2d Cir. 1994). This may be met by showing an absence of evidence in support of the non-moving party's claims or defenses at which point, the burden shifts to the non-moving party to show by affidavit or otherwise, that a genuine issue of material fact remains for the factfinder to resolve Celotex, 477 U.S. 317.

III. DISCUSSION

A. Motion for Summary Judgment

1. Sham Exception to Noerr-Pennington Immunity

The Defendants move for summary judgment on two grounds: their Citizen Petition to the FDA was not objectively baseless and the Plaintiffs after months of discovery were unable to show that the Citizen Petition delayed the generic manufacturers' ANDAs. As explained in my prior opinion, the Noerr-Pennington doctrine provides immunity for conduct aimed at persuading the government of a position or expressing views concerning government decisions even if the

conduct interferes with competition; such conduct is classic petitioning activity protected by the First Amendment and such actions may not be limited by the Sherman Act. See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 137-138 (1961) and United Mine Workers v. Pennington, 381 U.S. 657 (1965). Thus a valid attempt to procure government action, even when initiated to attain a competitive advantage, is protected by Noerr-Pennington. However, such immunity is not absolute and does not protect the filing of "sham litigation." Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 516, 30 L. Ed. 2d 642, 92 S. Ct. 609 (1972). The Supreme Court defined a two-step inquiry into a sham filing claim:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. . . . [Second,] a court should focus on whether the baseless suit conceals an attempt to interfere directly with a competitor's business relationships through the use of the governmental process -- as opposed to the outcome of that process -- as an anticompetitive weapon. . . . [Thus, to obviate Noerr immunity, a plaintiff must] demonstrate both the objective and the subjective components of a sham.

Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61 (1993). "The relevant issue is whether the legal challenges are brought pursuant to a policy of starting legal proceedings without regard for the merits [but rather] for the purpose of injuring a market rival." California Motor Transp., 404 U.S. at 512; PrimeTime 24 Joint Venture v. National Broadcasting Co., 219 F.3d 92, 101 (2d Cir. 2000).

The Defendants move for summary judgment based on the first step, the objective prong analysis, arguing that the petition was objectively reasonable. No reasonable pharmaceutical manufacturer could have expected Aventis's Citizen Petition to succeed on the merits because Aventis ignored the law by requesting relief that was contrary to existing law and precedent. As I held previously, ignoring the law, filing administrative or legal actions that do not request reasonable extensions or development of the law and mischaracterization of the relevant issues or legal standards exemplify objectively baseless actions. Mot. to Dismiss, at 7.

The information at hand and the circumstances surrounding the filing of the Citizen Petition belie any reasonable expectation of success on the merits, as required by Prof'l Real Estate Investors. Defendants made three requests for relief to the FDA that they knew were contrary to FDA regulations, and practice. First, they demanded that the generic manufacturers of leflunomide be forced to produce their own 100 mg tablet in order to succeed with their ANDAs. But Defendants knew that the FDA had long permitted ANDAs to receive approval to

market certain, although not all, dosage strengths of a branded drug (Def. Ex. 73), and Aventis failed to cite authority to the contrary. (Def. Ex. 27, Gardella Tr. 221:23-222:22; Def. Ex. 31, Parker Tr. 180:7-22.) Defendants also knew that the generic maintenance doses would be just as safe and effective as Arava's maintenance doses whether or not the generics provided their own loading doses.[5] (Def. Ex. 8, Dr. Karen Simpson, Aventis rheumatologist, Tr. 102:12-107:13.) They also knew that no study established the greater efficacy of a loading dose versus non-use of a loading dose. (Def. Ex. 8, Simpson Tr. 76:4-7.)

Second, Defendants demanded that if the generics tried to use a substitute of five 20 mg tablets to achieve the loading dose, then they must establish bioequivalence between those tablets to the single Arava 100 mg tablet. But Defendants knew that generics are not required to establish bioequivalence between different dosage strengths of the same drug. (Def. Ex. 31, Parker Tr. 140:20-142:4.)

Third, Defendants insisted that the generics should not be permitted to reference Aventis's 100 mg tablet in their labels. But Defendants knew that drug manufacturers were permitted under FDA regulations to cross-reference other drugs and dosages because they themselves did so in two instances. (Def. Ex. 73, FDA Denial of Petition.) The FDA specifically noted and informed Aventis that it had cross-referenced other brand drugs and strengths on Aventis's own generic and brand labels when it did not manufacture either the drug or the strength indicated.[6] More tellingly, Aventis permitted its generic partner, Prasco, to

[5] Though not appropriate for the objective prong analysis, throughout their memorandum Defendants insist that the reason for their having filed the Citizen Petition was their concern for safety, even though such statements are more appropriate for the subjective prong of the sham exception. To the extent that they raised these issues, and that it does implicate their knowledge of the need or lack thereof for the loading dose, the following internal reports and studies show that the loading dose was not necessarily safe or more effective than non-use of a loading dose. The Arava® label itself said the loading dose was recommended but also cautioned that the drug was safer without the loading dose for most users (Def. Ex. 19, March 2004 Arava label at 23). They knew that they themselves had ceased to supply the loading dose to pharmacies and retailers as doctors had abandoned the loading dose for safety reasons due to tolerability problems and risk of discontinuance (ASOF 60-64: Strobos Rep.; PEx. 18, 19 e-mails Dr. Steve Kovacs, Sanofi-Aventis Clinical Pharmacologist). They knew that at least one study found that Arava was safer without the loading dose (see Strobos Report) and many other internal reports cited safety concerns with adults and children (see Pl. Ex. 17, Dr. Kovacs and Dr. Jun Shi, Population Pharmacokinetics Report, August 21, 2003).

[6] The FDA letter states in relevant part:

> As does the approved labeling for Arava . . . approved labeling for generic leflunomide products would include the recommendation of using 100-mg tablets for the loading dose. . . . As reflected by existing precedents, ANDA sponsors may refer in their labeling to products they do not manufacture. . . . It is also not uncommon for brand name products to refer in their labeling to other drugs that are not provided by the sponsor of the brand name product (e.g., the labeling of

market 10 mg and 20 mg, but not 100 mg, dosages of leflunomide on July 29, 2005.[7] (Bennett Rep. ¶ 5.4.7.1; see also PEx. 35.) Defendants were fully aware that Prasco's label would simply include a reference to the Arava 100 mg loading dose. (PExs. 33-35[8], Bennett Rep. ¶ 5.4.7.1.)

No one who participated in the preparation of the Petition could cite authority to the effect that generics are prohibited from referencing another manufacturer's product in their label. (Def. Ex. 27, Gardella Tr. 188:8-189:6; Def. Ex. 31, Parker Tr. 74:17-75:19; 152:2-10; Def. Ex. 28, Fabbio Tr. 122:11-18; Def. Ex. 15, Nijveldt Tr. 76:3-9.) In fact, Defendants knew that the generics must copy the reference drug's labels, including dosage strengths of a drug that generics do not seek to manufacture. (Def. Ex. 31, Parker Tr. 72:13-73:25.)

Upon this record, it is clear that Defendants were fully aware that the relief they requested in their Petition was contrary to FDA law and practice and thus there are genuine issues of fact with respect to the Defendants' objective basis for filing the Petition.

2. Causation

Causation implicates such issues as standing or proximate cause and lack of causation-in fact is fatal to the merits of any antitrust claim; thus plaintiffs must be able to show that the injuries alleged would not have occurred but for the defendant's antitrust violation.[9] Argus v. Eastman Kodak Co., 801 F.2d 38, 41 (2d Cir. 1986). Defendants argue that there were alternative bases for the alleged delay of ANDA approvals, namely: 1) the cluster review of the ANDAs; and 2) the common deficiencies addressed and amended several times by the FDA for the generics. Defendants argue that the FDA would only approve the ANDAs as a cluster and even the ANDA filers thought it would be simultaneous. (Def. Mem. 23 citing internal e-mails of generic manufacturers.) Further, Defendants argue that since the last generic to agree to the NMT 0.02% TFMA level occurred on September 12, 2005, the approval the following day of all

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> Oncaspar, an Aventis product, recommends its use in combination with . . . products not made by Aventis . . .).

(Def. Ex. 73, at 6-7.)

[7] The drug was actually Arava® with a different stamp, and hence did not require an ANDA to be filed.

[8] From May 10-12, 2005 a series of internal Aventis emails confirmed that there was no requirement for its generic partner, Prasco, to produce the 100 mg leflunomide tablet, but the Arava version and loading dose information should be referenced in the generic partner label.

[9] Causation is a necessary element of any claim for relief under Section 4 of the Clayton Act, which is the provision for treble damages for antitrust injury to a private plaintiff. 15 U.S.C. § 15; Discover Financial Services, DFS v. Visa U.SA., Inc., 04cv7844, 2008 WL 4067445 (S.DN.Y. Aug. 26, 2008) (citing Argus v. Eastman Kodak Co., 801 F.2d 38, 41 (2d Cir. 1986)).

six generic applications shows that this was a cluster approval process and the FDA delayed it on its own, notwithstanding the Citizen Petition.

Whether or not the FDA reviewed the six ANDAs in a cluster, as a matter of policy, it appears questionable that the FDA would delay approval of one ANDA that was ready to market in order to await the approval of all in a cluster. Indeed, this would violate FDA regulations and the fundamental *raison d'être* of cluster review, which is to expedite introduction of cheaper generics into the marketplace. (Pl. Mem. 22-23 citing 21 U.S.C. §355(j)(4).)[10] Second, the deficiencies raised after March 31, 2005, the date of the Petition, were solely minor issues, not manufacturing or validation issues, and arguably could have been approved quickly pre- or post-approval via CBE-0 (changes-being-affected in zero days). The FDA treated these as "Minor" and "Telephone" amendments, which meant that the applications were substantially cleared and that any changes could have been resolved post-approval in the next Annual Report pursuant to FDA regulation 21 C.F.R. § 314.70. (see generally Bennett Rep.)

As stated above, the batches produced in May or June 2005 met all the ultimate specifications of the FDA notwithstanding the fact that the TFMA amendments were being agreed to through September. On this record, it appears that there was in effect nothing else to block the applications; at a minimum this is a jury question. Finally, the FDA expressly stated to the ANDA applicants that they would not receive approval while it addressed the Citizen Petition and numerous statements of the FDA and studies showed that the FDA in fact slows down review of applications in the face of a Citizen Petition, even if ultimately baseless. Thus, the motion for summary judgment on both the objective prong of the sham exception to Noerr-Pennington immunity and causation must be denied.

B. Motion to Exclude Expert Testimony of Martha M. Bennett

Not surprisingly, Defendants move to exclude the testimony of the Plaintiff's expert witness, Martha M. Bennett,[11] who has opined that 1) the FDA's review and approval of the ANDA's would have occurred faster had it not been for the Citizen Petition; and 2) the "FDA

[10] See also Dr. Scott Gottlieb, M.D., speech before Annual Generic Drug Forum, Apr. 7, 2006. (Def.Ex. 159.)

[11] Defendants do not challenge Ms. Bennett's credentials. "Ms. Bennett is currently an independent consultant on FDA matters, including technical and regulatory matters concerning ANDA's, and prior to that worked for FDA itself." (Pl. Opp. Mem. to Excl. Expert ¶ 3.) "She worked for the FDA for thirteen (13) years." (Id. ¶ 3.) "Ms. Bennett has taught and lectured extensively on FDA regulatory requirements and has reviewed hundreds of NDA's and ANDA's." (Id. ¶ 3.) "Half of the work she did with the FDA as a field investigator pertained to generic drugs." (Id. ¶ 4.) "She was involved in responding to approximately twenty CP's and has continued to be involved with CP's, particularly involving generic drugs, following her departure from FDA." (Id. ¶ 4.)

would have approved the ANDA's before (i) determining the specifications it would require for a potentially toxic impurity, and (ii) obtaining confirmation from the ANDA filers that their generic products would meet those specifications." (Def. Mem. Excl. Expert 6.)

Even though the "court must act as a gatekeeper and only admit expert testimony that is both relevant and reliable," Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), "the decision to admit expert testimony is left to the broad discretion of the trial judge and will be overturned only when manifestly erroneous." McCullock v. H.B. Fuller Co., 61 F. 3d 1038, 1042-43 (2d Cir. 1995). The standard to evaluate non-scientific expert testimony is whether the expert bases testimony upon professional studies or personal experience and employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field. Kumho Tire Ltd. v. Carmichael, 526 U.S. 137, (1999).

Bennett's methodology entailed review of the documents made available to her: the ANDA applications, the correspondence with the FDA, including the deficiency letters and responses, in light of FDA regulations, guidances, and practice. See In re Terazosin Hydrochloride Antitrust Litig., 2005 WL 5955699 (S.D. Fla. 2005). She also took into account her experience with Citizen Petitions while an employee at the FDA and recent public statements of the FDA regarding the delaying impact of Petitions to approval of generic drugs.[12] She looked at the status of applications at the time of the filing of the Citizen Petition and the FDA's own statement to the generics that on June 2, 2005 to the generics that it would not approve the ANDAs until it resolved the Citizen Petition.

Finally, Bennett reported that the generics had manufactured launch batches by June 2005 that met the ultimately more stringent specification standards for TFMA. (Pl. Mem. 12; see Bennett Rep.) Therefore, her theory that the remaining amendments to adopt the TFMA and dissolution specifications were merely paper changes, and thus could have complied with last minute specifications by CBE-0, is supported by FDA regulations and her experience. Therefore, these are also questions for the jury. Taking all this support together, I do not find

[12] See also Bennett Dep. Tr. 196 – explaining why ANDA review may slow down in face of a Citizen Petition: "Because the Citizen Petition may generate a higher pressure than the pressure to meet a deadline on an ANDA. Citizens Petitions can go to litigation and having worked on them and having written defenses for the agency's position, I remember spending time doing legal research and writing essentially briefs in response to Citizens Petitions just in the anticipation that our decision might go before a court." Bennett cites to numerous FDA reports, congressional hearings and bills focusing on this very issue.

that her opinion that the Citizen Petition delayed the review and approval of these ANDAs is unreliable and instead, I find that this is an issue of weight for the jury to resolve.

In accordance with FRE 702, Ms. Bennett explained her opinions and tied them to the actual application status for each ANDA, FDA express statements and communications with the generics. Moreover, Defendants have not shown that Bennett's testimony will be overly prejudicial under FRE 403 and their motion is denied.

C. Motion to Strike Plaintiffs' 56.1 Statement of Facts

Defendants argue that Plaintiffs' responses and additional statement of facts pursuant to Local Rule 56.1 are rife with argument and narrative, rather than simple admissions or denials and should be stricken. Goldstick v. The Hartford, Inc., 00cv8577, 2002 WL 1906029 (S.D.N.Y. Aug. 19, 2002). They also claim that the statements include assertions that relate solely to the subjective inquiry of the two-step "sham litigation" test in Prof'l Real Estate Investors, 508 U.S. at 63.

Local Civil Rule 56.1 provides that annexed to the Rule 56 motion shall be a separate, **short and concise statement of the material facts** by the movant and non-movant that demonstrate existence of a genuine issue to be tried. Each statement must be followed by a citation to evidence which would be admissible under FRCP 56(e).

While sometimes lengthy and not directly responsive to the Defendants' statements, Plaintiffs satisfied their duty to provide explain and provide support for their challenges of Defendants' statements. Parks v. Lebhar-Friedman, Inc., 04cv7133, 2008 WL 3833802 (S.D.N.Y. Aug. 11, 2008). While Plaintiffs concede to Aventis's objections to PEx. 98 and PEx. 122 for purposes of the summary judgment motion,[13] I find that the remaining 56.1 Responses and Additional Facts should not be stricken.

The statements refer to evidence which constitutes party admissions FRE 801(d)(2) or hearsay exceptions under FRE 803(6), (8), (17), for business records, public records, or market and commercial reports.[14] Furthermore, Plaintiffs' responses concerning the subjective prong of the sham exception, respond directly to Defendants' own statements. Clearly, those—both

[13] These are 1) FDA Law Blog June 7, 2007 and 2) Kaufman, "Petitions to FDA Sometimes Delay Generic Drugs" July 3, 2006.

[14] These items include the public agency statements of the FDA head concerning activities of the agency, Report to the House and Senate Committee on Appropriations to discuss the abuse of Citizen Petitions; Aventis's own intelligence reports forecasting entry of generics into the marketplace and strategy reports.

Plaintiffs' and Defendants'—can be disregarded for purposes of this motion, which is limited to the objective prong of the sham analysis and causation.

Acceptance of the 56.1 statements rests within this Court's broad discretion. Photopaint Techs., LLC v. Smartlens Corp., 335 F.3d 152, 155 n.2 (2d Cir. 2003); Holtz v. Rockefeller & Co., 258 F.3d 62, 73 (2d Cir. 2001). There is sufficient evidence outside of some of the more excessive responses to support my decision in the Rule 56 motion and to strike the statement would be fruitless. The motion is denied.

III. CONCLUSION

Defendants' Motion for Summary Judgment pursuant to Federal Rule of Civil Procedure 56 is denied. Defendants' Motions to Exclude Expert Martha M. Bennett and to strike Plaintiffs' Responses to Defendants' 56.1 Statement as well as the Plaintiffs' Statement of Additional Facts are also denied. The parties are directed to prepare for Trial commencing November 10, 2008. I direct the Clerk of the Court to close these motions and remove them from my docket.

SO ORDERED
October 14, 2008
New York, New York

U.S.D.J.